UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,132	10/17/2003	Avi J. Ashkenazi	P1134R2C4	2023

9157 7590 10/12/2007

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
KAUFMAN, CLAIRE M	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/688,132	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65 and 67-93* is/are pending in the application.

4a) Of the above claim(s) *65 and 77-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *65, 67-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112, First Paragraph

following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-76 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous Office action.

Applicants argue that references published after the filing of the instant application should not be applied by the examiner in the rejection of claims under 35 USC 112, first paragraph, in view of the rejections under 35 USC 102(e). The argument has been fully considered, but is not persuasive. According to MPEP 2164.05(a):

In general, the examiner should not use post-filing date references to demonstrate that the patent is non-enabling. Exceptions to this rule could occur if a later-dated reference provides evidence of what one skilled in the art would have known on or before the effective filing date of the patent application. In re Hogan, 559 F.2d 595, 605, 194 USPQ 527, 537 (CCPA 1977). If individuals of skill in the art state that a particular invention is not possible years after the filing date, that would be evidence that the disclosed invention was not possible at the time of filing and should be considered. In *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513-14 (Fed. Cir. 1993) an article published 5 years after the filing date of the application adequately supported the examiner's position that the physiological activity of certain viruses was sufficiently unpredictable so that a person skilled in the art would not have believed that the success with one virus and one animal could be extrapolated successfully to all viruses with all living organisms. Claims not directed to the specific virus and the specific animal were held nonenabled.

It is noted that at issue is enablement of an application not a patent, and there is no prohibition against using post-filing references in an enablement rejection. Second, the post-

filing date references relied upon by the examiner in the instant rejection under 35 USC 112, first paragraph, enablement, show (as in *Wright)* unpredictability of practicing the claimed invention to treat diseases and conditions as claimed. As stated in the previous Office action on page 3:

> [Wrobleweski et al. (Biochem. Pharmacol.2003)] found "DcR3 (1-218) did not bind FasL or inhibit FasL-mediated apoptosis, but maintained its ability to bind LIGHT and interrupt activities mediated through this ligand binding pathway" (p. 665, col, 1, 7 lines from bottom). The specification shows only full or mature DcR3 has the ability to block FasL-induced apoptosis (Example 10). There is no showing of a truncated form having that ability. Therefore, even assuming the method was enabled for using DcR3, (which as discussed immediately below, it is not agreed that it is) a polypeptide that did not comprise at least amino acids 24-300 or SEQ ID NO:1 would not be.

Further, as discussed in the previous Office action on page 4, the references of Paul et al., J. Neuroimmunol. 2004), Shi et al., Infect. Immunity, 2006), Maher et al. (Immunol. Cell Biol. 2002), Whiteside (Seminars Cancer Biol.2002) and Lamhamedi-Cherradi (J. Clin. Immunol.2001), all support unpredictability of the role of FasL in inflammation, since there is evidence for both a proinflammatory and immunosuppressive activity of FasL. It is maintained (see end of p. 4 of previous Office action) that inhibition of the activity of FasL with DcR3 "would cause unpredictable effects on inflammation or inflammatory diseases or disorders and could not be used to treat or prevent such."

As to the different requirements for 35 USC 112, first parargraph, and 102, the Court found in *In re Hafner*, 410 F.2d 1403 [161 USPQ 783] (CCPA 1969), that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or how to use for such a purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." The reasons is that section 112, "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." *Hafner*, 410 F2.d at 1405.

Priority

Applicants argue that the issue of priority should be held in abeyance because the USPTO is inconsistent when applying standards of determining enablement and utility for pending applications compared to patented applications applied as prior art. However, Applicants are reminded that something which is old does not become patentable upon the discovery of a new property. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best* , 195 USPQ 430, 433 (CCPA 1977). Therefore, knowledge that DcR3 binds FasL and is a soluble decoy receptor does not make it patentable if the prior art discloses a method of treating an inflammatory disease by administering DcR3 polypeptide as set forth in claim 67, for example. As discussed above in terms of the requirements of prior art, in *In re Hafner*, 410 F.2d 1403 [161 USPQ 783] (CCPA 1969), the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial utility or how to use for such a purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim." The reasons is that section 112, "provides that the specification must enable one skilled in the art to 'use' the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure." *Hafner*, 410 F2.d at 1405.

For the reasons of record, it is maintained that the effective filing date of the instant application is that of 60/094,640, filed 07/30/98.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before

November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 67, 68 and 71-74 remain rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,885,800 (Emery et al cited by Applicants) for the reasons set forth in the previous Office action:

US Patent 5,885,800 teaches the TR4 polypeptide (SEQ ID NO:2) which has a sequence identical to the DcR3 polypeptide (SEQ ID NO:1) of the instant application. Treating inflammation, inflammatory bowel disease and psoriasis using TR4 is also taught (col. 12, lines 26-30). Because treatment is also directed to Alzheimers disease and AIDS, subjects to be treated necessarily include humans (col. 12, lines 32-34).

Applicants argue that the Emery patent discloses only sequences for TR4 and speculative and prophetic uses for TR4, and does not have an enabling disclosure for TR4, including for the instantly claimed method. The argument has been fully considered, but is not persuasive. While there are no actual examples of treatment or prevention using the TR4 polypeptide nor is the mechanism by which TR4 can be used for treatment of inflammation or inflammatory diseases disclosed in '800, the claimed method is taught. An actual reduction to practice is not required for this to be an anticipatory reference. According to MPEP § 2122, utility need not be disclosed in a reference. "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)." Further, as stated in MEPE § 2121.01, the courts have found that:

> "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention not novel' or anticipated' within section 102, the stated test is whether a reference contains an enabling disclosure'... ." In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such

> possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985)

In the instant case, Emery et al. provides all that is necessary for the artisan of ordinary skill at the time the invention was made to practice the claimed invention.

Claims 67-76 remain rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0150583 (Gentz et al., cited by applicants) for the reasons set forth in the previous Office action:

US 2002/0150583 teaches TNFR-6α polypeptide (TR6, SEQ ID NO:2) which has the same sequence as DcR3 (SEQ ID NO:1) of the instant application. Also, taught is the use of disclosed polypeptides for the treatment of patients including humans (middle of [0386]). Treatment of inflammation and inflammatory diseases or disorders by administering TNFR-6α polypeptide is disclosed, including inflammatory bowel disease ([0460]) and psoriasis ([0457]). Also taught is TNFR-6α polypeptide fused to an immunoglobulin constant region (Fc) to treat or prevent diseases or conditions associated with inflammation ([0458]).

Applicants argue that a patent's effective filing date for the purpose of 35 USC 102(e) is based on sufficient disclosure under USC 112, first paragraph, for the subject matter in question. "...[T]he claims of the reference patent must be supported in the manner required by 35 U.S.C. § 112 in the priority application whose date is relied on to establish the prior art status of the patent. See *In re Wertheim,* 646 F2d 527, 209 USPQ 554 (SPA 1981); and MPEP 2136.03, sub-heading IV. The argument has been fully considered, but is not persuasive. As to MPEP 2136.03 (IV), this section deals with priority for a claimed invention. US 2002/0150583 is not trying to claim the instant invention. The issue is not the priority date for the claims in that pregrant publication. What is at issue if the benefit of priority it receives as a 35 USC 102(e) reference being relied upon in an art rejection. Similarly, *Wertheim* focused on carry-over of material. That is, if an application is a CIP, the claims in the CIP must find support in the disclosure of the parent in order to get priority to the parent filing date. However, here the focus

is not on the claims of US 2002/0150583 itself, but on the whether the disclosure supports anticipation of the claims in instant application 10/688,132. Material that an applicant in a 102(e) priority reference could have claimed (*i.e.*, is fully supported by the priority disclosure) can be used against another who later claims it. As stated previously, provisional application US 60/035,496 (1/14/97), to which US 2002/0150583 claims priority, supports a method for treatment of inflammatory bowel disease by administering an antagonist (p. 56, lines 34-35). US 60/035,496 discloses that HIV-induced apoptosis can be treated with an antagonist of the invention (paragraph bridging pages 55-56), and that an antagonist can be a soluble form of the TNFR-6α receptor (page 54, lines 28-37). Therefore, even though the mechanism of action of TNFR-6α was not appreciated in US 60/035,496, the disclosure supports the instantly claimed methods.

Applicants argue that neither priority application of US 2002/0150583 contains experimental data characterizing the activity or function of TNFR-6α nor discloses a ligand(s) of TNFR-6α. The argument has been fully considered, but is not persuasive. Experimental data is not required for anticipation or obviousness. The ability of TNFR-6α to bind FasL is not necessary for anticipation by US 2002/0150583, because as stated above, "even though the mechanism of action of TNFR-6α was not appreciated in US 60/035,496, the disclosure supports the instantly claimed methods." The priority applications disclose treatment of an inflammatory disease by a soluble TNFR-6α receptor.

Applicants argue that the TNFR-6α priority application US 60/035,496 has a laundry list of conditions which the inventors speculate TNFR-6α may be used to treat, and as such does not provide support under 35 USC 112, first paragraph. Also, without disclosure of the function or activity of the receptor or identity of a ligand, '496 does not provide adequate written support or enable the instantly claimed methods. The argument has been fully considered, but is not persuasive. The '496 application teaches treating inflammatory bowel disease with soluble TNFR-6α . For this reasons and those discussed above, the priority applications of US 2002/0150583 provide support under 35 USC 112, first paragraph, for the instantly claimed methods even though the mechanisms of TNFR-6α activity were not disclosed.

Applicants argue that the '496 provisional application confirms that little of TNFR-6α structure or function was known, for example by the incorrect suggestion that TNFR-6α is a

membrane bound receptor and that it is structurally and functionally similar to TNFR-1 and -2. Applicants argue because of the low approximately 23% identity of TNFR-6α to TNFR-1 and-2, one cannot drawn inferences about TNFR-6α based on information that was available concerning TNFR-1 or -2. The argument has been fully considered, but is not persuasive. There is no prohibition against prophetic statements or disclosure of uses based on an incomplete understanding of a protein's structure or function. In the current case, it is maintained that the disclosure of US 2002/0150583 and its two immediate priority applications supports anticipation of the claimed methods.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.
Patent Examiner, Art Unit 1646
October 9, 2007

LORRAINE SPECTOR
PRIMARY EXAMINER